

Application No.: 10/004,732  
Amendment Dated: March 15, 2004  
Reply to Office Action of: January 16, 2004

In the Claims:

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. ~~[[deletion]]~~) and new text is identified in bold with underlining (e.g. new language).

1. (Original) An implantable medical electrical lead for electrical stimulation of body tissue adapted to be introduced through and released into body tissue employing an introducer having an introducer lumen, comprising:

a lead body extending between lead proximal and distal ends;

P proximal connector elements formed in a connector array in a proximal segment of the lead body;

P stimulation electrodes arranged in an electrode array extending proximally from the lead distal end through a distal segment of the lead body;

P lead conductors extending between the P connector elements and the P stimulation electrodes; and

a plurality of M tine elements formed in a tine element array extending through a segment of the lead proximal to the electrode array, each tine element comprising N flexible, pliant, tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, whereby the M x N tines are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally and release the tines to inhibit axial dislodgement of the P stimulation electrodes.

2. (Original) The implantable medical lead of Claim 1, wherein the tines of the tine elements are formed of a flexible bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.

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3. (Original) The implantable medical lead of Claim 1, wherein the tines of the tine elements are formed of a flexible implantable grade superelastic alloy.
4. (Original) The implantable medical lead of Claim 1, wherein the tine attachment sites of the M tine elements are separated longitudinally along the lead body in the tine element array by a distance that is substantially equal to or exceeds the tine length when folded proximally against the lead body so that the tines are not overlapping one another.
5. (Original) The implantable medical lead of Claim 1, wherein the tine attachment sites of each of the M tine elements are disposed in a common circumference of the lead body, and the tine attachment sites of adjoining tine elements along the lead body are radially offset from one another around the common circumference such that the tine free ends of the tines of each adjacent tine element engage against body tissue at radially and axially separated points along the tine element array.
6. (Original) The implantable medical lead of Claim 5, wherein tine lengths and tine widths are selected to enable the more distal N tines of more distal tine elements of the tine element array to be folded proximally alongside and interleaved with the adjacent more proximal tines of more proximal tine elements.
7. (Original) The implantable medical lead of Claim 6, wherein N tines of the M tine elements are equal in number.
8. (Original) The implantable medical lead of Claim 1, wherein N tines of the M tine elements are equal in number.
9. (Original) The implantable medical lead of Claim 1, wherein  $P > 1$ , and at least one of the P stimulation electrodes comprises an elongated, flexible electrode adapted to assume a curve when implanted in relation to body tissue.

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10. (Original) The implantable medical lead of Claim 1, wherein  $P = 1$ .
11. (Original) A medical electrical stimulation system comprising:  
an implantable pulse generator for providing medical electrical stimulation; and  
a medical electrical lead coupled to the implantable pulse generator for electrical stimulation of body tissue and adapted to be introduced through and released into body tissue employing an introducer having an introducer lumen,  
the medical electrical lead further comprising:  
a lead body extending between lead proximal and distal ends;  
P proximal connector elements formed in a connector array in a proximal segment of the lead body a coupled with the implantable pulse generator;  
P stimulation electrodes arranged in an electrode array extending proximally from the lead distal end through a distal segment of the lead body;  
P lead conductors extending between the P connector elements and the P stimulation electrodes; and  
a plurality of M tine elements formed in a tine element array extending through a segment of the lead proximal to the electrode array, each tine element comprising N flexible, pliant, tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, whereby the  $M \times N$  tines are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally and release the tines to inhibit axial dislodgement of the P stimulation electrodes.
12. (Original) The medical electrical stimulation system of Claim 11, wherein the tines of the tine elements are formed of a flexible bio-compatible plastic selected from the group consisting of medical grade polyurethane compounds and silicone rubber compounds.

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13. (Original) The medical electrical stimulation system of Claim 11, wherein the tines of the tine elements are formed of a flexible implantable grade superelastic alloy.
14. (Original) The medical electrical stimulation system of Claim 11, wherein the tine attachment sites of the M tine elements are separated longitudinally along the lead body in the tine element array by a distance that is substantially equal to or exceeds the tine length when folded proximally against the lead body so that the tines are not overlapping one another.
15. (Original) The medical electrical stimulation system of Claim 11, wherein the tine attachment sites of each of the M tine elements are disposed in a common circumference of the lead body, and the tine attachment sites of adjoining tine elements along the lead body are radially offset from one another around the common circumference such that the tine free ends of the tines of each adjacent tine element engage against body tissue at radially and axially separated points along the tine element array.
16. (Original) The medical electrical stimulation system of Claim 15, wherein tine lengths and tine widths are selected to enable the more distal N tines of more distal tine elements of the tine element array to be folded proximally alongside and interleaved with the adjacent more proximal tines of more proximal tine elements.
17. (Original) The medical electrical stimulation system of Claim 16, wherein N tines of the M tine elements are equal in number.
18. (Original) The medical electrical stimulation system of Claim 11, wherein N tines of the M tine elements are equal in number.
19. (Original) The medical electrical stimulation system of Claim 11, wherein  $P > 1$ , and at least one of the P stimulation electrodes comprises an elongated, flexible wire coil electrode adapted to assume a curve when implanted in relation to body tissue.

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20. (Original) The medical electrical stimulation system of Claim 11, wherein  $P = 1$ .

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

24. (Cancelled)

25. (Cancelled)

26. (Cancelled)

27. (Cancelled)

28. (Cancelled)

29. (Cancelled)

30. (Cancelled)

31. (Cancelled)

32. (Cancelled)

33. (Original) An implantable medical electrical lead for non-direct contact electrical stimulation of the sacral nerves comprising:

a lead body extending between lead proximal and distal ends, the lead body comprising a first proximal connector element, an elongated distal wire coil electrode, and a first lead

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conductor extending between the first proximal connector element and the wire coil electrode, whereby the wire coil electrode is capable of being inserted through a foramen of the sacrum into operative relation with a sacral nerve to provide stimulation to the sacral nerve without necessarily being in direct contact with the sacral nerve, the lead body further comprising:

a plurality of M tine elements formed in a tine element array extending through a segment of the lead proximal to the distal wire coil electrode, each tine element comprising N flexible, pliant, tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, whereby the M x N tines are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of an introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally and release the tines to inhibit axial dislodgement of the distal electrode.

34. (Original) The implantable medical electrical lead of Claim 33, wherein the lead body further comprises a second proximal connector element, a ring-shaped electrode spaced apart proximally from the distal wire coil electrode, and a second lead conductor extending between the second proximal connector element and the distal ring-shaped electrode.

35. (Original) An implantable medical electrical lead for non-direct contact electrical stimulation of the sacral nerves comprising:

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a lead body extending between lead proximal and distal ends, the lead body comprising a first proximal connector element, at least one distal electrode, and a first lead conductor extending between the first proximal connector element and the wire coil electrode, whereby the wire coil electrode is capable of being inserted through a foramen of the sacrum into operative relation with a sacral nerve to provide stimulation to the sacral nerve without necessarily being in direct contact with the sacral nerve, the lead body further comprising:

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a plurality of M tine elements formed in a tine element array extending through a segment of the lead proximal to the distal electrode, each tine element comprising N flexible, pliant, tines, each tine having a tine width and thickness and extending through a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, whereby the M x N tines are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of an introducer without overlapping one another and deploy outward to engage body muscle tissue when the introducer is withdrawn proximally and release the tines to inhibit axial dislodgement of a distal electrode.

36. (Original) The implantable medical electrical lead of Claim 35, wherein the lead body further comprises a second proximal connector element, a ring-shaped electrode spaced apart proximally from the distal electrode, and a second lead conductor extending between the second proximal connector element and the distal ring-shaped electrode.

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